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 RICHARD W. WIEKING
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 NORTHERN DISTRICT OF CALIFORNIA
 OAKLAND

IN THE UNITED STATES DISTRICT COURT
 FOR THE NORTHERN DISTRICT OF CALIFORNIA
 OAKLAND DIVISION

LEVI JONES, individually and on behalf
 of all others similarly situated,

Plaintiff,

v.

CONAGRA FOODS, INC.,

Defendant.

C12-01633

EDL

**CLASS ACTION AND
 REPRESENTATIVE ACTION**

**COMPLAINT FOR DAMAGES,
 EQUITABLE AND INJUNCTIVE RELIEF**

JURY TRIAL DEMANDED

Plaintiff, Levi Jones, through his undersigned attorneys, brings this lawsuit against ConAgra Foods, Inc. (hereinafter "ConAgra" or "Defendant") as to his own acts upon personal knowledge, and as to all other matters upon information and belief. In order to remedy the harm arising from Defendant's illegal conduct, which has resulted in unjust profits, Plaintiff brings this action on behalf of a class of California consumers who, within the last four years, purchased a ConAgra brand canned tomato or cooking spray product bearing a statement on its label indicating it was "100% natural," or a ConAgra brand canned tomato or cocoa product bearing a statement on its label indicating it or an ingredient it contained was a source of either Lycopene or an unnamed antioxidant (referred to herein as "Misbranded Food Products").

INTRODUCTION

1
2 1. Every day, millions of Americans purchase and consume packaged foods.
3 Identical federal and California laws require truthful, accurate information on the labels of
4 packaged foods. This case is about a company that flouts those laws. The law, however, is clear:
5 misbranded food cannot legally be manufactured, held, advertised, distributed, or sold.
6 Misbranded food is worthless as a matter of law, and purchasers of misbranded food are entitled
7 to a refund of their purchase price.

8 2. If a manufacturer is going to make a claim on a food label, the label must meet
9 certain legal requirements that help consumers make informed choices and ensure that they are
10 not misled. Defendant has made, and continues to make, false and deceptive claims in violation
11 of federal and California laws that govern the types of representations that can be made on food
12 labels. These laws recognize that reasonable consumers are likely to choose products claiming to
13 have a health or nutritional benefit over otherwise similar food products that do not claim such
14 benefits.

15 3. Identical federal and California laws regulate the content of labels on packaged
16 food. The requirements of the federal Food, Drug & Cosmetic Act ("FDCA") were adopted by
17 the California legislature in the Sherman Food Drug & Cosmetic Law (the "Sherman Law").
18 California Health & Safety Code § 109875, *et seq.* Under FDCA section 403(a), food is
19 "misbranded" if "its labeling is false or misleading in any particular," or if it does not contain
20 certain information on its label or in its labeling. 21 U.S.C. § 343(a). Under the FDCA, the term
21 "false" has its usual meaning of "untruthful," while the term "misleading" is a term of art.
22 Misbranding reaches not only false claims, but also those claims that might be technically true,
23 but still misleading. If any single representation in the labeling is misleading, the entire food is
24 misbranded, and no other statement in the labeling can cure a misleading statement.
25 "Misleading" is judged in reference to "the ignorant, the unthinking and the credulous who, when
26 making a purchase, do not stop to analyze." *United States v. El-O-Pathic Pharmacy*, 192 F.2d
27 62, 75 (9th Cir. 1951). Under the FDCA, it is not necessary to prove that anyone was actually
28 misled.

1 4. ConAgra, through its website, claims that it is “one of North America’s leading
2 food companies” and claims to have consumer brands in 97% of America’s households.
3 ConAgra’s major brands include but are not limited to Alexia®, Chef Boyardee®,
4 Fleischmann’s®, Healthy Choice®, Hunt’s®, Manwich®, Marie Callender’s®, Orville
5 Redenbacher’s®, PAM®, Parkay®, Peter Pan®, Ro*Tel®, Slim Jim®, Snack Pack®, Swiss
6 Miss®, Wesson®, and others.

7 5. Through its Hunt’s brand, ConAgra packages and sells canned tomatoes, including
8 Diced Tomatoes, Crushed Tomatoes, Stewed Tomatoes, Whole Tomatoes, Tomato Paste, Tomato
9 Puree, and Tomato Sauce, including variations of each. The canned tomato industry sometimes
10 refers to these as the “seven segments.” ConAgra sells cooking sprays through its Pam brand and
11 cocoa through its Swiss Miss brand.

12 6. As consumer preferences have begun to favor healthier options, ConAgra has
13 embarked on a health and wellness strategy that seeks to emphasize how its products are good for
14 a consumer and to reposition its products as a healthy option. In furtherance of its health and
15 wellness strategy, ConAgra utilizes unlawful, false and misleading nutrient content and health
16 claims to promote and market its Misbranded Food Products. ConAgra has also sought to appeal
17 to consumer preferences for natural and functional foods by including unlawful, false and
18 misleading “100% natural” claims, antioxidant claims and fresh claims on its Misbranded Food
19 Product labels and product related materials.

20 7. ConAgra’s reason for making such claims is driven by its pecuniary interests. As
21 stated by ConAgra in the Risk Factors section of the most recent annual report it filed with the
22 S.E.C.:

23 Consumer preferences evolve over time and the success of our food products
24 depends on our ability to identify the tastes and dietary habits of consumers and
25 to offer products that appeal to their preferences, including concerns of
26 consumers regarding health and wellness, obesity, product attributes, and
27 ingredients. Introduction of new products and product extensions requires
28 significant development and marketing investment. If our products fail to meet
consumer preference, or we fail to introduce new and improved products on a
timely basis, then the return on that investment will be less than anticipated and
our strategy to grow sales and profits with investments in marketing and
innovation will be less successful. Similarly, demand for our products could be
affected by consumer concerns regarding the health effects of ingredients such

1 as sodium, trans fats, sugar, processed wheat, or other product ingredients or
2 attributes.

3 8. In other ConAgra reports, ConAgra has identified the following risk to the
4 company:

5 Health care issues facing the United States and health-conscious consumer
6 expectations have put increasing pressure on the food industry to constantly
7 evaluate the nutritional profiles of its products. If our products fail to keep up
8 with health trends and consumer expectations, our business performance may
be negatively impacted.

9 ConAgra indicated that to address this risk it needed to:

10 ...stay aligned with consumer preferences and improve the nutritional value of
11 our products to establish a competitive advantage in the marketplace.

12 9. In furtherance of its health and wellness strategy ConAgra has utilized a number of
13 specific unlawful, improper, unauthorized, misleading and false antioxidant, nutrient content,
14 fresh and "100% natural" claims on its products' labels and labeling. These include:

15 A. "100% natural" claims on the labels of its Hunt's canned tomato
16 products and its Pam cooking spray products that contain ingredients that are
not natural according to the FDA;

17 B. "Free of artificial ingredients & preservatives" claims on the
18 labels of its Hunt's canned tomato products that contain artificial ingredients
19 and preservatives;

20 C. Antioxidant claims on the labels of its Hunt's canned tomato
21 products and Swiss Miss cocoa products which fail to meet the minimum
regulatory requirements for such antioxidant claims; and

22 D. Claims that ConAgra's Hunt's canned tomato products are
23 "potassium-rich" and "provide more than twice the potassium than other
24 common potassium sources" like bananas, potatoes, nonfat milk and orange
25 juice when such claims are false and are prohibited by federal and California
law.

26 10. ConAgra recognizes that health and nutritional claims drive food sales, and
27 actively promotes the purported health and nutritional benefits of its Misbranded Food Products,
28 notwithstanding the fact that such promotion violates federal and California law.

11. According to ConAgra “canned tomatoes users are nutrient-driven.” “These buyers are discriminating—often age 40 and older, with the maturity to understand that what they eat affects their wellness. They want to feed their families nutritionally sound meals, and as busy as they are, they willingly spend more time cooking than most. They value the short ingredients statements on Hunt's products, and they categorize canned tomatoes as a ‘less-processed’ food that deserves to be on their table.”

12. ConAgra also recognized that consumers were looking for natural options stating “Moms nowadays are looking for better-for-you products for their families. They want simple recipes, natural ingredients and quality at a fair price.”

13. ConAgra was aware, however, that because consumers only spend 5 to 10 seconds before making a decision to purchase, the “traditional brand blocking approach to this category [of sales] doesn't serve today's focused, time-pressed, health-seeking consumers.” For such consumers, label claims and other forms of advertising and marketing could help drive sales. Such consumers however would not have the time to examine claims or labels in detail.

14. ConAgra has made a number of specific claims about its canned tomato products including:

- A. Tomatoes are a health promoting food;
- B. Antioxidant properties lend tomatoes toward lowering risk for a number of chronic diseases and improving health status overall;
- C. Hunt's® Tomatoes are available in many varieties, including No Salt Added options, which makes it easy to incorporate the health benefits of tomatoes into your daily meals;
- D. Tomatoes are nutrient dense;
- E. Tomatoes are a package of phyto / bioactive nutrients associated with health;
- F. Tomatoes deliver on multiple consumer demands;
- G. Tomatoes offer Taste, Convenience, Calories, Cost, Health.

1 15. ConAgra specifically promotes the antioxidant properties and antioxidant health
2 benefits of its tomato-based canned products. ConAgra maintains the website
3 <http://www.conagrafoodsscienceinstitute.com>, which contains the following statements:

4
5 A. A natural source of antioxidants, Hunt's® tomatoes are
6 prepared and packed using a FlashSteam® process to remove the
7 peel;

8 B. Hunt's tomatoes provide:
9 • Highly bioavailable lycopene

10 C. Antioxidant properties lend tomatoes toward lowering risk
11 for a number of chronic diseases and improving health status
12 overall.

13 16. ConAgra also has issued press releases touting the healthy nature of its canned
14 tomato products, including that tomatoes "may have a measurable impact on heart disease
15 prevention" and contribute to "a significant decrease in blood pressure."
16 [http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-](http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1494219&highlight)
[newsArticle&ID=1494219&highlight.](http://media.conagrafoods.com/phoenix.zhtml?c=202310&p=irol-newsArticle&ID=1494219&highlight)

17 17. In promoting the purported benefits of its Misbranded Food Products, including
18 Hunt's canned tomato products, ConAgra claims it has adopted responsible marketing and
19 advertising policies. ConAgra claims to understand the importance of communicating
20 responsibly about their products.

21 18. Nevertheless, ConAgra has made, and continues to make, unlawful, false and
22 deceptive claims on its Misbranded Food Products in violation of federal and California laws that
23 govern the types of representations that can be made on food labels. In particular, in making its
24 unlawful antioxidant claims on its Misbranded Food Products, Defendant has violated nutrient
25 content labeling regulations and misbranding laws mandated by federal and California law. In
26 making its "100% Natural" and other claims, Defendant has violated a number of other food
27 labeling and misbranding laws mandated by federal and California law including those
28 prohibiting false or misleading label claims.

19. Defendant has made, and continues to make, unlawful claims on the food labels of their Misbranded Food Products that are prohibited by federal and California law and which render these products misbranded. Under federal and California law, Defendant's Misbranded Food Products, including Hunt's canned tomato products, cannot legally be manufactured, advertised, distributed, held or sold. Defendant's false and misleading labeling practices stem from its global marketing strategy. Thus, the violations and misrepresentations are similar across product labels and product lines.

PARTIES

20. Plaintiff Levi Jones is a resident of Santa Rosa, California who purchased Defendant's Misbranded Food Products in California during the four (4) years prior to the filing of this Complaint (the "Class Period").

21. Defendant ConAgra is a Delaware corporation with its principal place of business at One ConAgra Drive in Omaha, Nebraska 68102.

22. Defendant is a leading producer of retail food products, including the products described herein.

23. Defendant sells its Misbranded Food Products to consumers through grocery and other retail stores throughout California.

JURISDICTION AND VENUE

24. This Court has original jurisdiction over this action under 28 U.S.C. § 1332(d) because this is a class action in which: (1) there are over 100 members in the proposed class; (2) members of the proposed class have a different citizenship from Defendant; and (3) the claims of the proposed class members exceed \$5,000,000 in the aggregate.

25. The Court has jurisdiction over the federal claim alleged herein pursuant to 28 U.S.C. § 1331, because it arises under the laws of the United States.

26. The Court has jurisdiction over the California claims alleged herein pursuant to 28 U.S.C. § 1367, because they form part of the same case or controversy under Article III of the United States Constitution.

27. Alternatively, the Court has jurisdiction over all claims alleged herein pursuant to 28 U.S.C. § 1332, because the matter in controversy exceeds the sum or value of \$75,000, and is between citizens of different states.

28. The Court has personal jurisdiction over Defendant because a substantial portion of the wrongdoing alleged in this Complaint occurred in California, Defendant is authorized to do business in California, has sufficient minimum contacts with California, and otherwise intentionally avails itself of the markets in California through the promotion, marketing and sale of merchandise, sufficient to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.

29. Because a substantial part of the events or omissions giving rise to these claims occurred in this District and because the Court has personal jurisdiction over Defendant, venue is proper in this Court pursuant to 28 U.S.C. § 1391(a) and (b).

FACTUAL ALLEGATIONS

A. Identical California And Federal Laws Regulate Food Labeling

30. Food manufacturers are required to comply with federal and state laws and regulations that govern the labeling of food products. First and foremost among these is the FDCA and its labeling regulations, including those set forth in 21 C.F.R. § 101.

31. Pursuant to the Sherman Law, California has expressly adopted the federal labeling requirements as its own and indicated that “[a]ll food labeling regulations and any amendments to those regulations adopted pursuant to the federal act, in effect on January 1, 1993, or adopted on or after that date shall be the food regulations of this state.” California Health & Safety Code § 110100.

32. In addition to its blanket adoption of federal labeling requirements, California has also enacted a number of laws and regulations that adopt and incorporate specific enumerated federal food laws and regulations. For example, food products are misbranded under California Health & Safety Code § 110660 if their labeling is false and misleading in one or more particulars; they are misbranded under California Health & Safety Code § 110665 if their labeling fails to conform to the requirements for nutrient labeling set forth in 21 U.S.C. § 343(q)

1 and regulations adopted thereto; they are misbranded under California Health & Safety Code
2 § 110670 if their labeling fails to conform with the requirements for nutrient content and health
3 claims set forth in 21 U.S.C. § 343(r) and regulations adopted thereto; they are misbranded under
4 California Health & Safety Code § 110705 if words, statements and other information required
5 by the Sherman Law to appear on their labeling are either missing or not sufficiently
6 conspicuous; they are misbranded under California Health & Safety Code § 110735 if they are
7 represented as having special dietary uses but fail to bear labeling that adequately informs
8 consumers of their value for that use; and they are misbranded under California Health & Safety
9 Code § 110740 if they contain artificial flavoring, artificial coloring and chemical preservatives
10 but fail to adequately disclose that fact on their labeling.

11 **B. FDA Enforcement History**

12 33. In recent years the FDA has become increasingly concerned that food
13 manufacturers were disregarding food labeling regulations. To address this concern, the FDA
14 elected to take steps to inform the food industry of its concerns and to place the industry on
15 notice that food labeling compliance was an area of enforcement priority.

16 34. In October 2009, the FDA issued a Guidance For Industry: Letter regarding Point
17 Of Purchase Food Labeling ("2009 FOP Guidance"), to address its concerns about front of
18 package labels. The 2009 FOP Guidance advised the food industry: FDA's research has found
19 that with FOP labeling, people are less likely to check the Nutrition Facts label on the
20 information panel of foods (usually, the back or side of the package). It is thus essential that both
21 the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally
22 sound, well-designed to help consumers make informed and healthy food choices, and not be
23 false or misleading. The agency is currently analyzing FOP labels that appear to be misleading.
24 The agency is also looking for symbols that either expressly or by implication are nutrient
25 content claims. We are assessing the criteria established by food manufacturers for such symbols
26 and comparing them to our regulatory criteria.

27 It is important to note that nutrition-related FOP and shelf labeling, while
28 currently voluntary, is subject to the provisions of the Federal Food, Drug, and
Cosmetic Act that prohibit false or misleading claims and restrict nutrient

1 content claims to those defined in FDA regulations. Therefore, FOP and shelf
2 labeling that is used in a manner that is false or misleading misbrands the
3 products it accompanies. Similarly, a food that bears FOP or shelf labeling with
4 a nutrient content claim that does not comply with the regulatory criteria for the
claim as defined in Title 21 Code of Federal Regulations (CFR) 101.13 and
Subpart D of Part 101 is misbranded. We will consider enforcement actions
against clear violations of these established labeling requirements. . .

5 ... Accurate food labeling information can assist consumers in making healthy
6 nutritional choices. FDA intends to monitor and evaluate the various FOP
7 labeling systems and their effect on consumers' food choices and perceptions.
8 FDA recommends that manufacturers and distributors of food products that
include FOP labeling ensure that the label statements are consistent with FDA
9 laws and regulations. FDA will proceed with enforcement action against
10 products that bear FOP labeling that are explicit or implied nutrient content
requirements. FDA will also proceed with enforcement action where such FOP
11 labeling or labeling systems are used in a manner that is false or misleading.

12 35. The 2009 FOP Guidance recommended that “manufacturers and distributors of
13 food products that include FOP labeling ensure that the label statements are consistent with FDA
14 law and regulations” and specifically advised the food industry that it would “proceed with
15 enforcement action where such FOP labeling or labeling systems are used in a manner that is
16 false or misleading.”

17 36. Despite the issuance of the 2009 FOP Guidance, Defendant did not remove the
18 unlawful and misleading food labeling claims from their Misbranded Food Products.

19 37. On March 3, 2010, the FDA issued an “Open Letter to Industry from [FDA
20 Commissioner] Dr. Hamburg” (“Open Letter”). The Open Letter reiterated the FDA’s concern
21 regarding false and misleading labeling by food manufacturers. In pertinent part the letter stated:

22 In the early 1990s, the Food and Drug Administration (FDA) and the food
23 industry worked together to create a uniform national system of nutrition
24 labeling, which includes the now-iconic Nutrition Facts panel on most food
25 packages. Our citizens appreciate that effort, and many use this nutrition
26 information to make food choices. Today, ready access to reliable information
27 about the calorie and nutrient content of food is even more important, given the
prevalence of obesity and diet-related diseases in the United States. This need
28 is highlighted by the announcement recently by the First Lady of a coordinated
national campaign to reduce the incidence of obesity among our citizens,
particularly our children.

1 With that in mind, I have made improving the scientific accuracy and
2 usefulness of food labeling one of my priorities as Commissioner of Food and
3 Drugs. The latest focus in this area, of course, is on information provided on
4 the principal display panel of food packages and commonly referred to as
5 "front-of-pack" labeling. The use of front-of-pack nutrition symbols and other
6 claims has grown tremendously in recent years, and it is clear to me as a
7 working mother that such information can be helpful to busy shoppers who are
8 often pressed for time in making their food selections. ...

9 As we move forward in those areas, I must note, however, that there is one area
10 in which more progress is needed. As you will recall, we recently expressed
11 concern, in a "Dear Industry" letter, about the number and variety of label
12 claims that may not help consumers distinguish healthy food choices from less
13 healthy ones and, indeed, may be false or misleading.

14 At that time, we urged food manufacturers to examine their product labels in
15 the context of the provisions of the Federal Food, Drug, and Cosmetic Act that
16 prohibit false or misleading claims and restrict nutrient content claims to those
17 defined in FDA regulations. As a result, some manufacturers have revised their
18 labels to bring them into line with the goals of the Nutrition Labeling and
19 Education Act of 1990. Unfortunately, however, we continue to see products
20 marketed with labeling that violates established labeling standards.

21 To address these concerns, FDA is notifying a number of manufacturers that
22 their labels are in violation of the law and subject to legal proceedings to
23 remove misbranded products from the marketplace. While the warning letters
24 that convey our regulatory intentions do not attempt to cover all products with
25 violative labels, they do cover a range of concerns about how false or
26 misleading labels can undermine the intention of Congress to provide
27 consumers with labeling information that enables consumers to make informed
28 and healthy food choices

....

These examples and others that are cited in our warning letters are not
indicative of the labeling practices of the food industry as a whole. In my
conversations with industry leaders, I sense a strong desire within the industry
for a level playing field and a commitment to producing safe, healthy products.
That reinforces my belief that FDA should provide as clear and consistent
guidance as possible about food labeling claims and nutrition information in
general, and specifically about how the growing use of front-of-pack calorie
and nutrient information can best help consumers construct healthy diets.

I will close with the hope that these warning letters will give food
manufacturers further clarification about what is expected of them as they
review their current labeling. I am confident that our past cooperative efforts
on nutrition information and claims in food labeling will continue as we jointly
develop a practical, science-based front-of-pack regime that we can all use to
help consumers choose healthier foods and healthier diets.

1 38. Notwithstanding the Open Letter, Defendant continued to utilize unlawful food
2 labeling claims despite the express guidance of the FDA in the Open Letter.

3 39. In addition to its guidance to industry, the FDA has sent warning letters to
4 industry, including many of Defendant's peer food manufacturers for the same types of unlawful
5 nutrient content claims described above.

6 40. In these letters the FDA indicated that as a result of the same type of claims
7 utilized by the Defendant, products were in "violation of the Federal Food, Drug, and Cosmetic
8 Act ... and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR
9 101)" and were "misbranded within the meaning of section 403(r)(1)(A) because the product
10 label bears a nutrient content claim but does not meet the requirements to make the claim."

11 41. The warning letters were hardly isolated as the FDA has issued over 10 other
12 warning letters to other companies for the same type of food labeling claims at issue in this case.

13 42. The FDA stated that the agency not only expected companies that received
14 warning letters to correct their labeling practices but also anticipated that other firms would
15 examine their food labels to ensure that they are in full compliance with food labeling
16 requirements and make changes where necessary. ConAgra did not change the labels on its
17 Misbranded Food Products in response to the warning letters sent to other companies nor did it
18 change its labels on its Misbranded Food Products when it ultimately received a warning letter
19 from the FDA.

20 43. Defendant also has ignored the FDA's Guidance for Industry, A Food Labeling
21 Guide which details the FDA's guidance on how to make food labeling claims. Defendant
22 continues to utilize unlawful claims on the labels of its Misbranded Food Products. Despite all
23 warnings, Defendant's Misbranded Food Products continue to run afoul of FDA guidance as well
24 as federal and California law.

25 44. Despite the FDA's numerous warnings to industry, Defendant has continued to sell
26 products bearing unlawful food labeling claims without meeting the requirements to make them.

27
28

1 45. Plaintiff did not know, and had no reason to know, that the Defendant's
2 Misbranded Food Products were misbranded and bore food labeling claims despite failing to meet
3 the requirements to make those food labeling claims.

4 **C. Defendant's Food Products Are Misbranded**

5
6 46. Pursuant to Section 403 of the FDCA, a claim that characterizes the level of a
7 nutrient in a food is a "nutrient content claim" that must be made in accordance with the
8 regulations that authorize the use of such claims. 21 U.S.C. § 343(r)(1)(A). California expressly
9 adopted the requirements of 21 U.S.C. § 343(r) in § 110670 of the Sherman Law.

10 47. Nutrient content claims are claims about specific nutrients contained in a product.
11 They are typically made on food packaging in a font large enough to be read by the average
12 consumer. Because consumers rely upon these claims when making purchasing decisions, the
13 regulations govern what claims can be made in order to prevent misleading claims.

14 48. Section 403(r)(1)(A) of the FDCA governs the use of expressed and implied
15 nutrient content claims on labels of food products that are intended for sale for human
16 consumption. *See* 21 C.F.R. § 101.13.

17 49. 21 C.F.R. § 101.13 provides the general requirements for nutrient content claims,
18 which California has expressly adopted. California Health & Safety Code § 110100.

19 50. An "expressed nutrient content claim" is defined as any direct statement about the
20 level (or range) of a nutrient in the food (*e.g.*, "low sodium" or "contains 100 calories"). *See* 21
21 C.F.R. § 101.13(b)(1).

22 51. An "implied nutrient content claim" is defined as any claim that: (i) describes the
23 food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a
24 certain amount (*e.g.*, "high in oat bran"); or (ii) suggests that the food, because of its nutrient
25 content, may be useful in maintaining healthy dietary practices and is made in association with an
26 explicit claim or statement about a nutrient (*e.g.*, "healthy, contains 3 grams (g) of fat"). 21
27 C.F.R. § 101.13(b)(2)(i-ii).

1 **1. Defendant Makes Unlawful Nutrient Content Claims**

2 52. FDA regulations authorize use of a limited number of defined nutrient content
3 claims. In addition to authorizing the use of only a limited set of defined nutrient content terms on
4 food labels, FDA's regulations authorize the use of only certain synonyms for these defined terms.
5 If a nutrient content claim or its synonym is not included in the food labeling regulations it cannot
6 be used on a label. Only those claims, or their synonyms, that are specifically defined in the
7 regulations may be used. All other claims are prohibited. 21 CFR 101.13(b).

8 53. Only approved nutrient content claims will be permitted on the food label, and all
9 other nutrient content claims will misbrand a food. It should thus be clear which type of claim is
10 prohibited and which permitted. Manufacturers are on notice that the use of an unapproved
11 nutrient content claim is prohibited conduct. 58 FR 2302. In addition, 21 USC 343(r)(2) prohibits
12 using unauthorized undefined terms and declares foods that do so to be misbranded.

13 54. In order to appeal to consumer preferences, Defendant has repeatedly made
14 unlawful nutrient content claims about Lycopene and unnamed antioxidants that fail to utilize one
15 of the limited defined terms. These nutrient content claims are unlawful because they failed to
16 comply with the nutrient content claim provisions in violation of 21 C.F.R. §§ 101.13 and 101.54,
17 which have been incorporated in California's Sherman Law. To the extent that the terms used to
18 describe Lycopene and unnamed antioxidants are deemed to be a synonym for a defined term like
19 "contain" the claim would still be unlawful because, as these nutrients do not have established
20 daily values, they cannot serve as the basis for a term that has a minimum daily value threshold.

21 55. Similarly, the regulations specify absolute and comparative levels at which foods
22 qualify to make these claims for particular nutrients (*e.g.*, .low fat, . . . more vitamin C.) and list
23 synonyms that may be used in lieu of the defined terms. Certain implied nutrient content claims
24 (*e.g.*, .healthy.) also are defined. The daily values (DVs) for nutrients that the FDA has
25 established for nutrition labeling purposes have application for nutrient content claims, as well.
26 Claims are defined under current regulations for use with nutrients having established DVs;
27 moreover, relative claims are defined in terms of a difference in the percent DV of a nutrient
28 provided by one food as compared to another. *See. e.g.* 21 C.F.R. §§ 101.13 and 101.54.

1 56. Defendant has repeatedly made unlawful nutrient content claims about Lycopene
2 and potassium that fail to utilize one of the limited defined terms appropriately. These nutrient
3 content claims are unlawful because they fail to comply with the nutrient content claim provisions
4 in violation of 21 C.F.R. §§ 101.13 and 101.54, which have been incorporated in California's
5 Sherman Law.

6 57. Claims that ConAgra's Hunt's canned tomato products are "potassium-rich" are
7 unlawful because Hunt's canned tomato products do not meet the minimum nutrient level
8 threshold to make such a claim which is 20 percent or more of the RDI (Reference Daily Intake
9 or Recommended Daily Intake) or the DRV (Daily Reference Value) of potassium per reference
10 amount customarily consumed. Similarly, claims that ConAgra's Hunt's canned tomato products
11 "provide" or "contain" Lycopene are unlawful because Lycopene does not have an RDI and
12 therefore Hunt's canned tomato products do not meet the minimum nutrient level threshold to
13 make such a claim which is 10 percent or more of the RDI or the DRV per reference amount
14 customarily consumed. Claims that ConAgra's Hunt's canned tomato products "have more than
15 twice the potassium than other common potassium sources" like bananas, potatoes, nonfat milk
16 and orange juice fail to meet the criteria for such a claim as well. 21 C.F.R. §§ 101.13 and 101.54.

17 58. In addition, claims that ConAgra's Hunt's canned tomato products have "more"
18 than twice the potassium than other common potassium sources" like potatoes, nonfat milk and
19 orange juice are literally false and misleading and another reason the Hunt's tomato products are
20 misbranded.

21 59. Claims that ConAgra products contain or are made with an ingredient that is
22 known to contain a particular nutrient, or is prepared in a way that affects the content of a
23 particular nutrient in the food, can only be made if it "good source" of the nutrient that is
24 associated with the ingredient or type of preparation. Thus, statements on canned tomato product
25 labels that Lycopene is found in tomatoes trigger a "good source" (10 percent or more of the RDI
26 or the DRV per reference amount customarily consumed) which Lycopene and tomatoes cannot
27 demonstrate. Similarly, statements that on cocoa product labels that unnamed antioxidants are
28 found in cocoa trigger a "good source" (10 percent or more of the RDI or the DRV per reference

amount customarily consumed) which the cocoa and unnamed antioxidants cannot demonstrate.
21 C.F.R. § 101.65(c)(3).

60. The nutrient content claims regulations discussed above are intended to ensure that consumers are not misled as to the actual or relative levels of nutrients in food products.

61. Defendant has violated these referenced regulations. Therefore, Defendant's Misbranded Food Products are misbranded as a matter of federal and California law and cannot be sold or held because they are legally worthless.

2. Defendant Makes Unlawful Antioxidant Claims

62. On its product labels, ConAgra touts that its canned tomato products contain antioxidants such as Lycopene. For example, the product label for Hunt's "Diced Tomatoes" states:



63. Federal and California regulations regulate antioxidant claims as a particular type of nutrient content claim. Specifically, 21 C.F.R. § 101.54(g) contains special requirements for nutrient claims that use the term “antioxidant”:

(1) the name of the antioxidant must be disclosed;

(2) there must be an established RDI for that antioxidant, and if not, no “antioxidant” claim can be made about it;

(3) the label claim must include the specific name of the nutrient that is an antioxidant and cannot simply say “antioxidants” (*e.g.*, “high in antioxidant vitamins C and E”), *see* 21 C.F.R. § 101.54(g)(4);

(4) the nutrient that is the subject of the antioxidant claim must also have recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions, *see* 21 C.F.R. § 101.54(g)(2);

(5) the antioxidant nutrient must meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for “High” claims, “Good Source” claims, and “More” claims, respectively. For example, to use a “High” claim, the food would have to contain 20% or more of the Daily Reference Value (“DRV”) or RDI per serving. For a “Good Source” claim, the food would have to contain between 10-19% of the DRV or RDI per serving, *see* 21 C.F.R. § 101.54(g)(3); and

(6) the antioxidant nutrient claim must also comply with general nutrient content claim requirements such as those contained in 21 C.F.R. § 101.13(h) that prescribe the circumstances in which a nutrient content claim can be made on the label of products high in fat, saturated fat, cholesterol or sodium.

64. Defendant’s package labels for all canned tomato products represent that the antioxidant Lycopene is contained in the tomatoes.

65. The antioxidant labeling for Defendant’s canned tomato products violates federal and California law. The antioxidant claims on the packages of these products violate federal and

California law (1) because there are no RDIs for Lycopene, the antioxidant being touted, and (2) because Defendant lacks adequate scientific evidence that the claimed antioxidant nutrients participate in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions after they are eaten and absorbed from the gastrointestinal tract.

66. The FDA has issued at least one warning letter relating to the use of a claim of a Lycopene claim for tomato products indicating that because “[t]here is no established reference value for Lycopene” a nutrient claim for Lycopene is unlawful. As such Lycopene cannot serve as the basis for the type of antioxidant claim made on the Hunt’s canned tomato products.

67. Similarly, ConAgra’s antioxidant claims on its Swiss Miss cocoa products are also unlawful and render the products misbranded because the labels simply represent that an unnamed antioxidant is contained in the cocoa:

- (1) the name of the antioxidant is not disclosed;
- (2) there is no established RDI for that antioxidant;
- (3) the label claim does not include the specific name of the nutrient that is an antioxidant;
- (4) the nutrient that is the subject of the antioxidant claim does not have recognized antioxidant activity, *i.e.*, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions; and
- (5) the antioxidant nutrient does not meet the requirements for nutrient content claims in 21 C.F.R. § 101.54(b), (c), or (e) for “High” claims, “Good Source” claims, and “More” claims, respectively.

68. In addition to the Hirzel letter (Exhibit A), the FDA has issued at least 6 other warning letters addressing similar unlawful antioxidant nutrient content claims. Defendant knew or should have known of these FDA warning letters.

69. For these reasons, Defendant's antioxidant claims at issue in this Complaint are misleading and in violation of 21 C.F.R. § 101.54 and California law, and the products at issue are misbranded as a matter of law. Misbranded products cannot be legally manufactured, advertised, distributed, held or sold, and are legally worthless.

3. Defendant Makes Unlawful "100% NATURAL" Claims

70. Seeking to profit from consumers' desire for natural food products, ConAgra has falsely represented its Hunt's canned tomato products and Pam Cooking spray products as all natural when that is not true. On the principal display panel of its product labels, ConAgra claims that such products are "100% Natural."

71. The back panel of ConAgra's product labels for its Hunt's canned tomato products lists citric acid as an ingredient, and sometimes also list calcium chloride. The product label for Hunt's Diced Tomatoes lists both citric acid and calcium chloride.

72. Upon information and belief, some of ConAgra's competitors in the canned tomato product market also include citric acid and/or calcium chloride as ingredients, but those competitors do not make a "100% natural" claim on the product labels.

73. Upon information and belief, some of ConAgra's competitors in the canned or packaged tomato product market do not include citric acid or calcium chloride in their tomato products.

74. ConAgra itself produces non-canned tomato products like ketchup that do not contain citric acid or calcium chloride.

75. The FDA has sent warning letters relating to the use of a "Natural" label when a product contains citric acid and/or calcium chloride.

76. The FDA has determined – specifically with respect to canned tomato products – that "the addition of calcium chloride and citric acid to these products preclude use of the term 'natural' to describe this product."

77. On August 29, 2001, the FDA sent a letter to Hirzel Canning Company ("Hirzel warning letter" attached hereto as Exhibit A). The FDA specifically found that "labels for canned tomato products manufactured by" Hirzel were "in violation of Section 403 of the Federal Food

1 Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101-
 2 Food Labeling.” Among other reasons, the Hirzel warning letter stated in pertinent part:

3
 4 [The product] labels bear the term “All NATURAL,” but
 5 according to the ingredient statements, calcium chloride and citric
 6 acid are added to the products. We have not established a
 7 regulatory definition for the term “natural,” however; we discussed
 8 its use in the [preamble] to the food labeling final regulations (58
 9 Federal Register 2407, January 6, 1993). FDA’s policy regarding
 10 the use “natural,” means that nothing artificial or synthetic has
 11 been included in, or has been added to, a food that would not
 12 normally be expected to be in the food. Therefore, the addition of
 13 calcium chloride and citric acid to these products preclude use of
 14 the term “natural” to describe this product.

15 <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178343.htm>

16 78. Defendant knew or should have known of the Hirzel warning letter. Because the
 17 Defendant’s products contain the same ingredients prohibited by the FDA in other tomato
 18 products, the use of the claim “100% NATURAL” on Defendant’s tomato product labels is false
 19 and misleading, and therefore these products are misbranded under section 403(a)(1) of the Act.

20 79. On August 16, 2001, the FDA sent a warning letter to Oak Tree Farm Dairy, Inc.
 21 (“Oak Tree warning letter” attached hereto as Exhibit B). The letter “found serious violations” of
 22 the Federal Food, Drug, and Cosmetic Act and Title 21, Code of Federal Regulations, Part 101 –
 23 Food Labeling (21 CFR 101), and stated in pertinent part:

24 The term “all natural” on the “OAKTREE ALL NATURAL
 25 LEMONADE” label is inappropriate because the product contains
 26 potassium sorbate. Although FDA has not established a regulatory
 27 definition for “natural,” we discussed its use in the preamble to the
 28 food labeling final regulations (58 Federal Register 2407, January
 6, 1993, copy enclosed). FDA’s policy regarding the use of
 “natural,” means nothing artificial or synthetic has been included
 in, or has been added to, a food that would not normally be
 expected to be in the food. The same comment applies to use of
 the terms “100 % NATURAL” and “ALL NATURAL” on the
 “OAKTREE REAL BREWED ICED TEA” label because it
 contains citric acid.

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2001/ucm178712.htm>

1 Defendant knew or should have known of the Oak Tree warning letter.

2 80. On November 16, 2011, the FDA sent a warning letter to ConAgra's own
3 subsidiary, Alexia Foods, Inc., informing Alexia of its failure to comply with the requirements of
4 the FDCA and its regulations ("Alexia Warning Letter," attached hereto as Exhibit C). The
5 Alexia Warning Letter stated, in pertinent part:

6
7 The U.S. Food and Drug Administration (FDA) has reviewed the
8 labels for your Alexia brand Roasted Red Potatoes & Baby
9 Portabella Mushrooms products. Based on our review, we have
10 concluded that these products are in violation of the Federal Food,
11 Drug, and Cosmetic Act (the Act). You can find copies of the Act
12 and the FDA regulations through links in FDA's home page
13 at <http://www.fda.gov>.

14 Your Alexia brand Roasted Red Potatoes & Baby Portabella
15 Mushrooms product is misbranded within the meaning of section
16 403(a)(1) of the Act [21 U.S.C. 343(a)(1)], which states that a food
17 shall be deemed to be misbranded if its labeling is false or
18 misleading in any particular. The phrase "All Natural" appears at
19 the top of the principal display panel on the label. FDA considers
20 use of the term "natural" on a food label to be truthful and non-
21 misleading when "nothing artificial or synthetic...has been
22 included in, or has been added to, a food that would not normally
23 be expected to be in the food." [58 FR 2302, 2407, January 6,
24 1993].

25 Your Alexia brand Roasted Red Potatoes & Baby Portabella
26 Mushrooms product contains disodium dihydrogen pyrophosphate,
27 which is a synthetic chemical preservative. Because your products
28 contain this synthetic ingredient, the use of the claim "All Natural"
on this product label is false and misleading, and therefore your
product is misbranded under section 403(a)(1) of the Act.

We note that your Alexia brand products market a number of food
products with the "All Natural" statement on the label. We
recommend that you review all of your product labels to be
consistent with our policy to avoid additional misbranding of your
food products.

This letter is not intended to be an all-inclusive review of your
products and their labeling. It is your responsibility to ensure that
all of your products and labeling comply with the Act and its
implementing regulations. You should take prompt action to
correct the violations cited in this letter. Failure to do so may

1 result in enforcement action without further notice. Such action
2 may include, but is not limited to, seizure or injunction.

3 [http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/u
4 cm281118.htm](http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/cm281118.htm)

5 Defendant knew or should have known of the Alexia warning letter.

6 81. In its rule-making and warning letters to manufacturers, as described herein, the
7 FDA has repeatedly stated its policy to restrict the use of the term “natural” in connection with
8 added color, synthetic substances, and flavors as provided in 21 C.F.R. § 101.22.

9 82. The FDA has also repeatedly affirmed its policy regarding the use of the term
10 “natural” as meaning that nothing artificial or synthetic has been included in, or has been added
11 to, a food that would not normally be expected to be in the food.

12 83. The FDA considers use of the term “natural” on a food label to be truthful and
13 non-misleading when “nothing artificial or synthetic...has been included in, or has been added to,
14 a food that would not normally be expected to be in the food.” *See* 58 FR 2302, 2407, January 6,
15 1993.

16 84. Any coloring or preservative can preclude the use of the term “natural” even if the
17 coloring or preservative is derived from natural sources. The FDA distinguishes between natural
18 and artificial flavors in 21 C.F.R. § 101.22.

19 85. The FDA has sent out numerous warning letters concerning this issue. *See, e.g.,*
20 Exhibit A (August 29, 2001 FDA warning letter to Hirzel Canning Company relating to citric
21 acid or calcium chloride in tomato products); Exhibit B (August 16, 2001 FDA warning letter to
22 Oak Tree Farm Dairy relating to citric acid); and Exhibit C (November 16, 2011 FDA warning
23 letter to Alexia relating to synthetic chemical preservatives). Defendant is aware of these FDA
24 warning letters.

25 86. Defendant has unlawfully labeled a number of its products as being “100%
26 NATURAL” when they actually contain artificial ingredients and/or chemical preservatives.
27 These include the Defendant’s canned tomato products.

28 87. According to standardized requirements for canned tomatoes (21 C.F.R. §
155.190) citric acid may only be used for acidification purposes while calcium chloride may only

1 be used as a firming agent. Given that these uses are both artificial and a form of preservation, the
2 label statement "free of artificial ingredients & preservatives" is both false and misleading and
3 renders the Hunt's canned tomato products misbranded.

4 88. Defendant includes the phrase "100% NATURAL" at the top of the principal
5 display panel on the product labels of its Hunt's brand canned tomato products, despite the fact
6 that Defendant's canned tomato products contain the ingredients citric acid and/or calcium
7 chloride objected to by the FDA.

8 89. The National Advertising Division of the Council of Better Business Bureaus has
9 determined that ConAgra Foods should discontinue the claim certain of its tomato related claims
10 because in connection with the term "100% Natural" they might falsely leave consumers with the
11 impression that Hunt's tomato products were prepared from fresh unprocessed ingredients.

12 90. Until very recently, Defendant included the phrase "100% NATURAL" on the
13 principal display panel and other parts of the product labels of its Pam brand cooking sprays
14 which contained unnatural propellant.

15 91. Defendant has also made the same illegal claims on their websites and advertising
16 in violation of federal and California law.

17 92. A reasonable consumer would expect that when Defendant labels its products as
18 "100% NATURAL," the product's ingredients are "natural" as defined by the federal government
19 and its agencies. A reasonable consumer would also expect that when Defendant labels its
20 products as "100% NATURAL," the product ingredients are "natural" under the common use of
21 that word. A reasonable consumer would understand that "100% NATURAL" products do not
22 contain synthetic, artificial, or excessively processed ingredients.

23 93. Consumers are thus misled into purchasing and paying a premium for Defendant's
24 products with unnatural ingredients that are not "100% NATURAL" as falsely represented on
25 their labeling.

26 94. Defendant's products in this respect are misbranded under federal and California
27 law. Misbranded products cannot be legally sold or held and are legally worthless.
28

4. **Defendant Makes Unlawful “Free Of Artificial Ingredients & Preservatives” And Fresh Claims**

95. According to standardized requirements for canned tomatoes (21 C.F.R. § 155.190) citric acid may only be used for acidification purposes while calcium chloride may only be used as a firming agent. Given that these uses are both artificial and a form of preservation, the label statement “free of artificial ingredients & preservatives” is both false and misleading and renders the Hunt’s canned tomato products misbranded.

96. Hunt’s repeatedly claims that its tomato products have a “fresh taste.” For example, Hunt’s website describes the “vine-ripened fresh taste of Hunt’s tomatoes.” Under 21 C.F.R. § 101.95, the word “fresh,” when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation. The restrictions on the use of the term “fresh” “pertain to any use of the subject terms in a brand name and use as a sensory modifier” such as “fresh taste.” Given the thermal processing of Hunt’s FlashSteam process and the addition of the chemicals citric acid and calcium chloride, the use of the term “fresh taste” is deceptive and misleading.

97. The label of Hunt’s canned tomato products bears a FlashSteam Freshness symbol that appears to depict a raw unskinned tomato with beads of water on it.. Hunt’s claims that:

Only Hunt’s tomatoes are peeled with FlashSteam, our proprietary natural steam process that maintains the natural tomato goodness of every tomato in our Diced, Whole, and Stewed varieties. Some brands peel their tomatoes using lye or other harsh chemicals. FlashSteam, however, is a process that’s completely chemical-free—our Diced, Whole, and Stewed tomatoes are treated to nothing more harsh than a steam treatment.

Notwithstanding the claim that the process is “completely chemically free” at some point in the process the chemicals citric acid and calcium chloride are introduced to the tomato products. Given the addition of the preservatives and chemicals and the other processing the Hunt’s canned tomato products have been subjected to, the FlashSteam “freshness” claim is deceptive and misleading.

1 98. Moreover, Hunt's also asserts:

2 For diced, whole and stewed tomatoes, Hunt's unique flash-steam process helps
3 keep in the flavor and color of tomatoes picked at their peak of ripeness. This
4 allows Hunt's varieties to deliver the high nutritional profile and fresh taste that
canned tomatoes consumers desire.

5 This use of the term "fresh taste" despite the FlashSteam process and the chemicals that are added
6 to the tomato products by Hunt's is deceptive and misleading for the reasons stated above.

7 The National Advertising Division of the Council of Better Business Bureaus has
8 determined that ConAgra Foods should discontinue the claim certain of its tomato related claims
9 because in connection with the term "100% Natural" they might falsely leave consumers with the
10 impression that Hunt's tomato products were prepared from fresh unprocessed ingredients.

11 **D. Defendant Has Violated California Law**

12 99. Defendant has manufactured, advertised, distributed and sold products that are
13 misbranded under California law. Misbranded products cannot be legally manufactured,
14 advertised, distributed, or sold or held and are legally worthless as a matter of law.

15 100. Defendant has violated California Health & Safety Code §§ 109885 and 110390
16 which make it unlawful to disseminate false or misleading food advertisements that include
17 statements on products and product packaging or labeling or any other medium used to directly or
18 indirectly induce the purchase of a food product.

19 101. Defendant has violated California Health & Safety Code § 110395 which makes it
20 unlawful to manufacture, sell, deliver, hold or offer to sell any misbranded food.

21 102. Defendant has violated California Health & Safety Code § 110398 which makes it
22 unlawful to deliver or proffer for delivery any food that has been falsely advertised.

23 103. Defendant has violated California Health & Safety Code § 110660 because its
24 food products are misbranded in one or more ways, as follows:

25 a. They are misbranded under California Health & Safety Code § 110665
26 because their labeling fails to conform to the requirements for nutrient labeling set forth in 21
27 U.S.C. § 343(q) and the regulations adopted thereto;

28

b. They are misbranded under California Health & Safety Code § 110670 because their labeling fails to conform with the requirements for nutrient content and health claims set forth in 21 U.S.C. § 343(r) and the regulations adopted thereto; and

c. They are misbranded under California Health & Safety Code § 110705 because words, statements and other information required by the Sherman Law to appear on their labeling either are missing or not sufficiently conspicuous.

104. Defendant has violated California Health & Safety Code § 110760 which makes it unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is misbranded.

105. Defendant has violated California Health & Safety Code § 110765 which makes it unlawful for any person to misbrand any food.

106. Defendant has violated California Health & Safety Code § 110770 which makes it unlawful for any person to receive in commerce any food that is misbranded or to deliver or proffer for delivery any such food.

107. Defendant has violated the standard set by 21 C.F.R. § 101.2, which has been incorporated by reference in the Sherman Law, by failing to include on their product labels the nutritional information required by law.

108. Defendant has violated the standards set by 21 CFR §§ 101.13, 101.54, and 101.65 which have been adopted by reference in the Sherman Law, by including unauthorized antioxidant and nutrient content claims on their products.

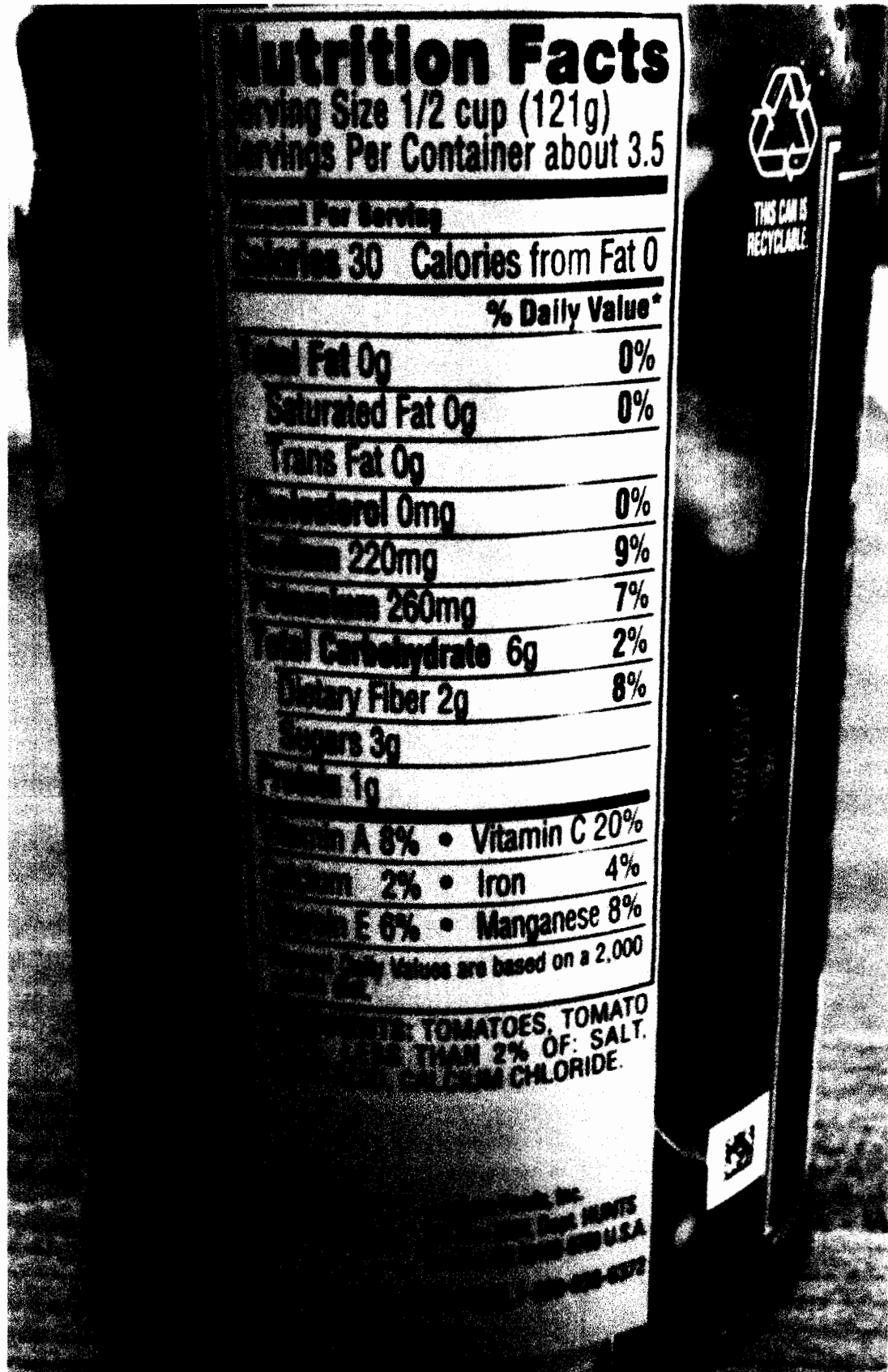
D. Plaintiff Purchased Defendant's Misbranded Food Products

109. Plaintiff cares about the nutritional content of food and seeks to maintain a healthy diet.

110. Plaintiff purchased Defendant's Misbranded Food Products at issue in this Complaint, including Hunt's canned tomatoes products, on occasions during the Class Period.

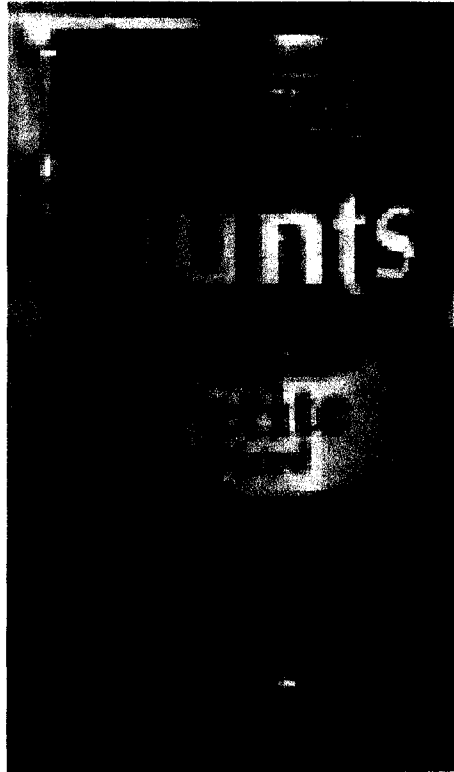
111. Plaintiff purchased Defendant's Misbranded Food Products, including Hunt's Petite Diced Tomatoes in a 14.5 oz. can.

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112. Plaintiff read the labels on Defendant's Misbranded Food Products including the "100% Natural" claim; the Lycopene antioxidant nutrient content claim; the "free of artificial ingredients & preservatives" claim; and the FlashSteam freshness claim before purchasing them.

113. Plaintiff relied on Defendant's package labeling including the "100% Natural" claim; the Lycopene antioxidant nutrient content claim; the "free of artificial ingredients & preservatives" claim; and the FlashSteam freshness claim, and based and justified the decision to purchase Defendant's Misbranded Food Products in substantial part on Defendant's package labeling including the "100% Natural" claim; the Lycopene antioxidant nutrient content claim; the "free of artificial ingredients & preservatives" claim; and the FlashSteam freshness claim.

114. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's products were misbranded as set forth herein, and would not have bought the products had he known the truth about them.

115. At point of sale, Plaintiff did not know, and had no reason to know, that Defendant's "100% Natural" claim; the Lycopene antioxidant nutrient content claim; the "free of

1 artificial ingredients & preservatives” claim; and the FlashSteam freshness claim on the
 2 products’ labels were unlawful as set forth herein, and would not have bought the products had
 3 he known the truth about them.

4 116. As a result of Defendant’s misrepresentations, Plaintiff and thousands of others in
 5 California purchased the products at issue.

6 117. Defendant’s labeling, advertising, and marketing as alleged herein is false and
 7 misleading and designed to increase sales of the products at issue. Defendant’s
 8 misrepresentations are part of an extensive labeling, advertising and marketing campaign, and a
 9 reasonable person would attach importance to Defendant’s representations in determining
 10 whether to purchase the products at issue.

11 118. A reasonable person would attach importance to whether Defendant’s products
 12 were legally salable and capable of legal possession and to Defendant’s representations about
 13 these issues in determining whether to purchase the products at issue. Plaintiff would not have
 14 purchased the Defendant’s Misbranded Food Products had he known they were not capable of
 15 being legally sold or held.

16 **CLASS ACTION ALLEGATIONS**

17 119. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil
 18 Procedure 23(b)(2) and 23(b)(3) on behalf of the following class:

19 All persons in California who, within the last four years, purchased a ConAgra
 20 brand canned tomato or cooking spray product bearing a statement on its label
 21 indicating it was “100% natural,” or a ConAgra brand canned tomato or cocoa
 product bearing a statement on its label indicating it or an ingredient it contained
 was a source of either Lycopene or an unnamed antioxidant (the “Class”).

22 120. The following persons are expressly excluded from the Class: (1) Defendant and
 23 its subsidiaries and affiliates; (2) all persons who make a timely election to be excluded from the
 24 proposed Class; and (3) governmental entities; and (4) the Court to which this case is assigned
 25 and its staff.

26 121. This action can be maintained as a class action because there is a well-defined
 27 community of interest in the litigation and the proposed Class is easily ascertainable.
 28

122. Numerosity: Based upon Defendant's publicly available sales data with respect to the misbranded products at issue, it is estimated that the Class numbers in the thousands, and that joinder of all Class members is impracticable.

123. Common Questions Predominate: This action involves common questions of law and fact applicable to each Class member that predominate over questions that affect only individual Class members. Thus, proof of a common set of facts will establish the right of each Class member to recover. Questions of law and fact common to each Class member include, for example:

- a. Whether Defendant engaged in unfair, unlawful or deceptive business practices by failing to properly package and label their Misbranded Food Products sold to consumers;
- b. Whether the food products at issue were misbranded or unlawfully packaged and labeled as a matter of law;
- c. Whether Defendant made unlawful and misleading antioxidant claims with respect to their food products sold to consumers;
- d. Whether Defendant made unlawful and misleading nutrient content claims with respect to their food products sold to consumers;
- e. Whether Defendant made unlawful and misleading "100% Natural" claims with respect to their food products sold to consumers;
- f. Whether Defendant violated California Bus. & Prof. Code § 17200 *et seq.*, California Bus. & Prof. Code § 17500 *et seq.*, the Consumer Legal Remedies Act, Cal. Civ. Code. § 1750 *et seq.*, and the Sherman Law;
- g. Whether Plaintiff and the Class are entitled to equitable and/or injunctive relief;
- h. Whether Defendant's unlawful, unfair and/or deceptive practices harmed Plaintiff and the Class; and
- i. Whether Defendant was unjustly enriched by its deceptive practices.

124. Typicality: Plaintiff's claims are typical of the claims of the Class because Plaintiff bought Defendant's Misbranded Food Products during the Class Period. Defendant's unlawful, unfair and/or fraudulent actions concern the same business practices described herein irrespective of where they occurred or were experienced. Plaintiff and the Class sustained similar

1 injuries arising out of Defendant's conduct in violation of California law. The injuries of each
2 member of the Class were caused directly by Defendant's wrongful conduct. In addition, the
3 factual underpinning of Defendant's misconduct is common to all Class members and represents
4 a common thread of misconduct resulting in injury to all members of the Class. Plaintiff's claims
5 arise from the same practices and course of conduct that give rise to the claims of the Class
6 members and are based on the same legal theories.

7 125. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class.
8 Neither Plaintiff nor Plaintiff's counsel have any interests that conflict with or are antagonistic to
9 the interests of the Class members. Plaintiff has retained highly competent and experienced class
10 action attorneys to represent their interests and those of the members of the Class. Plaintiff and
11 Plaintiff's counsel have the necessary financial resources to adequately and vigorously litigate
12 this class action, and Plaintiff and counsel are aware of their fiduciary responsibilities to the Class
13 members and will diligently discharge those duties by vigorously seeking the maximum possible
14 recovery for the Class.

15 126. Superiority: There is no plain, speedy or adequate remedy other than by
16 maintenance of this class action. The prosecution of individual remedies by members of the
17 Class will tend to establish inconsistent standards of conduct for Defendant and result in the
18 impairment of Class members' rights and the disposition of their interests through actions to
19 which they were not parties. Class action treatment will permit a large number of similarly
20 situated persons to prosecute their common claims in a single forum simultaneously, efficiently
21 and without the unnecessary duplication of effort and expense that numerous individual actions
22 would engender. Further, as the damages suffered by individual members of the Class may be
23 relatively small, the expense and burden of individual litigation would make it difficult or
24 impossible for individual members of the Class to redress the wrongs done to them, while an
25 important public interest will be served by addressing the matter as a class action. Class
26 treatment of common questions of law and fact would also be superior to multiple individual
27 actions or piecemeal litigation in that class treatment will conserve the resources of the Court and
28 the litigants, and will promote consistency and efficiency of adjudication.

127. The prerequisites to maintaining a class action for injunctive or equitable relief pursuant to Fed. R. Civ. P. 23(b)(2) are met as Defendant has acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive or equitable relief with respect to the Class as a whole.

128. The prerequisites to maintaining a class action pursuant to Fed. R. Civ. P. 23(b)(3) are met as questions of law or fact common to class members predominate over any questions affecting only individual members, and a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.

129. Plaintiff and Plaintiff's counsel are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

CAUSES OF ACTION

FIRST CAUSE OF ACTION

Business and Professions Code § 17200, *et seq.* Unlawful Business Acts and Practices

130. Plaintiff incorporates by reference each allegation set forth above.

131. Defendant's conduct constitutes unlawful business acts and practices.

132. Defendant sold Misbranded Food Products in California during the Class Period.

133. Defendant is a corporation and, therefore, is a "person" within the meaning of the Sherman Law.

134. Defendant's business practices are unlawful under § 17200, *et seq.* by virtue of Defendant's violations of the advertising provisions of the Sherman Law (Article 3) and the misbranded food provisions of the Sherman Law (Article 6).

135. Defendant's business practices are unlawful under § 17200, *et seq.* by virtue of Defendant's violations of § 17500, *et seq.*, which forbids untrue and misleading advertising.

136. Defendant's business practices are unlawful under § 17200, *et seq.* by virtue of Defendant's violations of the Consumer Legal Remedies Act, Cal. Civ. Code. § 1750 *et seq.*

137. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless.

138. As a result of Defendant's illegal business practices, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and to restore to any Class Member any money paid for the Misbranded Food Products.

139. Defendant's unlawful business acts present a threat and reasonable continued likelihood of injury to Plaintiff and the Class.

140. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

SECOND CAUSE OF ACTION
Business and Professions Code § 17200, et seq.
Unfair Business Acts and Practices

141. Plaintiff incorporates by reference each allegation set forth above.

142. Defendant's conduct as set forth herein constitutes unfair business acts and practices.

143. Defendant sold Misbranded Food Products in California during the Class Period.

144. Plaintiff and members of the Class suffered a substantial injury by virtue of buying Defendant's Misbranded Food Products that they would not have purchased absent Defendant's illegal conduct as set forth herein.

145. Defendant's deceptive marketing, advertising, packaging and labeling of its Misbranded Food Products and its sale of unsalable Misbranded Food Products that were illegal to possess was of no benefit to consumers, and the harm to consumers and competition is substantial.

146. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being legally sold or held and that were legally worthless.

147. Plaintiff and the Class who purchased Defendant's Misbranded Food Products had no way of reasonably knowing that the products were misbranded and were not properly marketed, advertised, packaged and labeled, and thus could not have reasonably avoided the injury each of them suffered.

148. The consequences of Defendant's conduct as set forth herein outweighs any justification, motive or reason therefor. Defendant's conduct is and continues to be illegal and contrary to public policy, and is substantially injurious to Plaintiff and the Class.

149. As a result of Defendant's conduct, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

THIRD CAUSE OF ACTION
Business and Professions Code § 17200, *et seq.*
Fraudulent Business Acts and Practices

150. Plaintiff incorporates by reference each allegation set forth above.

151. Defendant's conduct as set forth herein constitutes fraudulent business practices under California Business and Professions Code sections § 17200, *et seq.*

152. Defendant sold Misbranded Food Products in California during the Class Period.

153. Defendant's misleading marketing, advertising, packaging and labeling of the Misbranded Food Products and misrepresentation that the products were salable, capable of legal possession and not misbranded was likely to deceive reasonable consumers, and in fact, Plaintiff and members of the Class were deceived. Defendant has engaged in fraudulent business acts and practices.

154. Defendant's fraud and deception caused Plaintiff and the Class to purchase Defendant's Misbranded Food Products that they would otherwise not have purchased had they known the true nature of those products.

155. Defendant sold Plaintiff and the Class Misbranded Food Products that were not capable of being sold or held legally and that were legally worthless.

156. As a result of Defendant's conduct as set forth herein, Plaintiff and the Class, pursuant to Business and Professions Code § 17203, are entitled to an order enjoining such future conduct by Defendant, and such other orders and judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

FOURTH CAUSE OF ACTION
Business and Professions Code § 17500, *et seq.*
Misleading and Deceptive Advertising

157. Plaintiff incorporates by reference each allegation set forth above.

158. Plaintiff asserts this cause of action for violations of California Business and Professions Code § 17500, *et seq.* for misleading and deceptive advertising against Defendant.

159. Defendant sold Misbranded Food Products in California during the Class Period.

160. Defendant engaged in a scheme of offering Misbranded Food Products for sale to Plaintiff and members of the Class by way of, *inter alia*, product packaging and labeling, and other promotional materials. These materials misrepresented and/or omitted the true contents and nature of Defendant's Misbranded Food Products. Defendant's advertisements and inducements were made within California and come within the definition of advertising as contained in Business and Professions Code § 17500, *et seq.* in that such product packaging and labeling, and promotional materials were intended as inducements to purchase Defendant's Misbranded Food Products and are statements disseminated by Defendant to Plaintiff and the Class that were intended to reach members of the Class. Defendant knew that these statements were misleading and deceptive as set forth herein.

161. In furtherance of its plan and scheme, Defendant prepared and distributed within California and nationwide via product packaging and labeling, and other promotional materials, statements that misleadingly and deceptively represented the ingredients contained in and the

1 nature of Defendant's Misbranded Food Products. Plaintiff and the Class necessarily and
2 reasonably relied on Defendant's materials, and were the intended targets of such representations.

3 162. Defendant's conduct in disseminating misleading and deceptive statements in
4 California and nationwide to Plaintiff and the Class was and is likely to deceive reasonable
5 consumers by obfuscating the true ingredients and nature of Defendant's Misbranded Food
6 Products in violation of the "misleading prong" of California Business and Professions Code §
7 17500, *et seq.*

8 163. As a result of Defendant's violations of the "misleading prong" of California
9 Business and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the
10 expense of Plaintiff and the Class. Misbranded products cannot be legally sold or held and are
11 legally worthless.

12 164. Plaintiff and the Class, pursuant to Business And Professions Code § 17535, are
13 entitled to an order enjoining such future conduct by Defendant, and such other orders and
14 judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any
15 money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

16
17 **FIFTH CAUSE OF ACTION**
18 **Business and Professions Code § 17500, *et seq.***
Untrue Advertising

19 165. Plaintiff incorporates by reference each allegation set forth above.

20 166. Plaintiff asserts this cause of action against Defendant for violations of California
21 Business and Professions Code § 17500, *et seq.*, regarding untrue advertising.

22 167. Defendant sold Misbranded Food Products in California during the Class Period.

23 168. Defendant engaged in a scheme of offering Misbranded Food Products for sale to
24 Plaintiff and the Class by way of product packaging and labeling, and other promotional
25 materials. These materials misrepresented and/or omitted the true contents and nature of
26 Defendant's Misbranded Food Products. Defendant's advertisements and inducements were
27 made in California and come within the definition of advertising as contained in Business and
28 Professions Code §17500, *et seq.* in that the product packaging and labeling, and promotional

1 materials were intended as inducements to purchase Defendant's Misbranded Food Products, and
 2 are statements disseminated by Defendant to Plaintiff and the Class. Defendant knew that these
 3 statements were untrue.

4 169. In furtherance of their plan and scheme, Defendant prepared and distributed in
 5 California and nationwide via product packaging and labeling, and other promotional materials,
 6 statements that falsely advertise the ingredients contained in Defendant's Misbranded Food
 7 Products, and falsely misrepresented the nature of those products. Plaintiff and the Class were the
 8 intended targets of such representations and would reasonably be deceived by Defendant's
 9 materials.

10 170. Defendant's conduct in disseminating untrue advertising throughout California and
 11 nationwide deceived Plaintiff and members of the Class by obfuscating the contents, nature and
 12 quality of Defendant's Misbranded Food Products in violation of the "untrue prong" of California
 13 Business and Professions Code § 17500.

14 171. As a result of Defendant's violations of the "untrue prong" of California Business
 15 and Professions Code § 17500, *et seq.*, Defendant has been unjustly enriched at the expense of
 16 Plaintiff and the Class. Misbranded products cannot be legally sold or held and are legally
 17 worthless.

18 172. Plaintiff and the Class, pursuant to Business and Professions Code § 17535, are
 19 entitled to an order enjoining such future conduct by Defendant, and such other orders and
 20 judgments which may be necessary to disgorge Defendant's ill-gotten gains and restore any
 21 money paid for Defendant's Misbranded Food Products by Plaintiff and the Class.

22 **SIXTH CAUSE OF ACTION**

23 **Consumers Legal Remedies Act, Cal. Civ. Code §1750, et seq.**

24 173. Plaintiff incorporates by reference each allegation set forth above.

25 174. This cause of action is brought pursuant to the CLRA. This cause of action does
 26 not currently seek monetary relief and is limited solely to injunctive relief. Plaintiff intends to
 27 amend this Complaint to seek monetary relief in accordance with the CLRA after providing
 28 Defendant with notice pursuant to Cal. Civ. Code § 1782.

1 175. At the time of any amendment seeking damages under the CLRA, Plaintiff will
2 demonstrate that the violations of the CLRA by Defendant were willful, oppressive and
3 fraudulent, thus supporting an award of punitive damages.

4 176. Consequently, Plaintiff and the Class will be entitled to actual and punitive
5 damages against Defendant for its violations of the CLRA. In addition, pursuant to Cal. Civ.
6 Code § 1782(a)(2), Plaintiff and the Class will be entitled to an order enjoining the above-
7 described acts and practices, providing restitution to Plaintiff and the Class, ordering payment of
8 costs and attorneys' fees, and any other relief deemed appropriate and proper by the Court
9 pursuant to Cal. Civ. Code § 1780.

10 177. Defendant's actions, representations and conduct have violated, and continue to
11 violate the CLRA, because they extend to transactions that are intended to result, or which have
12 resulted, in the sale of goods or services to consumers.

13 178. Defendant sold Misbranded Food Products in California during the Class Period.

14 179. Plaintiff and members of the Class are "consumers" as that term is defined by the
15 CLRA in Cal. Civ. Code §1761(d).

16 180. Defendant's Misbranded Food Products were and are "goods" within the meaning
17 of Cal. Civ. Code §1761(a).

18 181. By engaging in the conduct set forth herein, Defendant violated and continues to
19 violate Section 1770(a)(5), of the CLRA, because Defendant's conduct constitutes unfair methods
20 of competition and unfair or fraudulent acts or practices in that they misrepresent the particular
21 ingredients, characteristics, uses, benefits and quantities of the goods.

22 182. By engaging in the conduct set forth herein, Defendant violated and continues to
23 violate Section 1770(a)(7) of the CLRA, because Defendant's conduct constitutes unfair methods
24 of competition and unfair or fraudulent acts or practices in that it misrepresents the particular
25 standard, quality or grade of the goods.

26 183. By engaging in the conduct set forth herein, Defendant violated and continues to
27 violate Section 1770(a)(9) of the CLRA, because Defendant's conduct constitutes unfair methods
28

1 of competition and unfair or fraudulent acts or practices in that it advertises goods with the intent
2 not to sell the goods as advertised.

3 184. By engaging in the conduct set forth herein, Defendant has violated and continues
4 to violate Section 1770(a)(16) of the CLRA, because Defendant's conduct constitutes unfair
5 methods of competition and unfair or fraudulent acts or practices in that it represents that a
6 subject of a transaction has been supplied in accordance with a previous representation when they
7 have not.

8 185. Plaintiff requests that the Court enjoin Defendant from continuing to employ the
9 unlawful methods, acts and practices alleged herein pursuant to Cal. Civ. Code § 1780(a)(2). If
10 Defendant is not restrained from engaging in these practices in the future, Plaintiff and the Class
11 will continue to suffer harm.

12 **SEVENTH CAUSE OF ACTION**
13 **Restitution Based on Unjust Enrichment/Quasi-Contract**

14 186. Plaintiff incorporates by reference each allegation set forth above.

15 187. As a result of Defendant's unlawful, fraudulent and misleading labeling,
16 advertising, marketing and sales of Defendant's Misbranded Food Products, Defendant was
17 enriched at the expense of Plaintiff and the Class.

18 188. Defendant sold Misbranded Food Products to Plaintiff and the Class that were not
19 capable of being sold or held legally and which were legally worthless. It would be against
20 equity and good conscience to permit Defendant to retain the ill-gotten benefits they received
21 from Plaintiff and the Class, in light of the fact that the products were not what Defendant
22 purported them to be. Thus, it would be unjust and inequitable for Defendant to retain the benefit
23 without restitution to Plaintiff and the Class of all monies paid to Defendant for the products at
24 issue.

25 189. As a direct and proximate result of Defendant's actions, Plaintiff and the Class
26 have suffered damages in an amount to be proven at trial.

EIGHTH CAUSE OF ACTION
Beverly-Song Act (Cal. Civ. Code § 1790, *et seq.*)

190. Plaintiff incorporates by reference each allegation set forth above.

191. Plaintiff and members of the Class are “buyers” as defined by Cal. Civ. Code § 1791(b).

192. Defendant is a “manufacturer” and “seller” as defined by Cal. Civ. Code § 1791(j) & (l).

193. Defendant’s food products are “consumables” as defined by Cal. Civ. Code § 1791(d).

194. Defendant’s nutrient and health content claims constitute “express warranties” as defined by Cal. Civ. Code § 1791.2.

195. Defendant, through its package labels, create express warranties by making the affirmation of fact and promising that its Misbranded Food Products comply with food labeling regulations under federal and California law.

196. Despite Defendant’s express warranties regarding its food products, it does not comply with food labeling regulations under federal and California law.

197. Defendant breached its express warranties regarding its Misbranded Food Products in violation of Cal. Civ. Code § 1790, *et seq.*

198. Defendant sold Plaintiff and members of the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless.

199. As a direct and proximate result of Defendant’s actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial pursuant to Cal. Civ. Code § 1794.

200. Defendant’s breaches of warranty were willful, warranting the recovery of civil penalties pursuant to Cal. Civ. Code § 1794.

NINTH CAUSE OF ACTION
Magnuson-Moss Act (15 U.S.C. § 2301, *et seq.*)

201. Plaintiff incorporates by reference each allegation set forth above.

202. Plaintiff and members of the Class are “consumers” as defined by 15 U.S.C. § 2301(3).

203. Defendant is a “supplier” and “warrantor” as defined by 15 U.S.C. § 2301(4) & (5).

204. Defendant's food products are "consumer products" as defined by 15 U.S.C. § 2301(1).

205. Defendant's nutrient and health content claims constitute "express warranties."

206. Defendant, through its package labels, create express warranties by making the affirmation of fact and promising that its Misbranded Food Products comply with food labeling regulations under federal and California law.

207. Despite Defendant's express warranties regarding its food products, it does not comply with food labeling regulations under federal and California law.

208. Defendant breached its express warranties regarding its Misbranded Food Products in violation of 15 U.S.C. §§ 2301, *et seq.*

209. Defendant sold Plaintiff and members of the Class Misbranded Food Products that were not capable of being sold or held legally and which were legally worthless.

210. As a direct and proximate result of Defendant's actions, Plaintiff and the Class have suffered damages in an amount to be proven at trial.

JURY DEMAND

Plaintiff hereby demands a trial by jury of his claims.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, and on behalf of the general public, prays for judgment against Defendant as follows:

A. For an order certifying this case as a class action and appointing Plaintiff and his counsel to represent the Class;

B. For an order awarding, as appropriate, damages, restitution or disgorgement to Plaintiff and the Class for all causes of action other than the CLRA, as Plaintiff does not seek monetary relief under the CLRA, but intends to amend his Complaint to seek such relief;

C. For an order requiring Defendant to immediately cease and desist from selling its

1 Misbranded Food Products in violation of law; enjoining Defendant from continuing to market,
2 advertise, distribute, and sell these products in the unlawful manner described herein; and
3 ordering Defendant to engage in corrective action;

4 D. For all equitable remedies available pursuant to Cal. Civ. Code § 1780;

5 E. For an order awarding attorneys' fees and costs;

6 F. For an order awarding punitive damages;

7 G. For an order awarding pre-and post-judgment interest; and

8 H. For an order providing such further relief as this Court deems proper.

9
10 Dated: April 2, 2012

Respectfully submitted,

11
12 By: Pierce Gore

BEN F. PIERCE GORE

Ben F. Pierce Gore (SBN 128515)

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U.S. Department of Health & Human Services

U.S. Food & Drug Administration

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
 Cincinnati District Office
 Central Region
 6751 Steger Drive
 Cincinnati, OH 45237-3097
 Telephone: (513) 679-2700
 FAX: (513) 679-2771

August 29, 2001
 WARNING LETTER
 CERTIFIED MAIL
 RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
 Hirzel Canning Company
 411 Lemoyne Road
 Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of your firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(1) of the Act in that its labeling is false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is "fresh," when in fact it has been thermally processed. The Food and drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Dei Fratelli Fresh & Read CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei ratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact the have been thermally processed. In addition, according to the ingredient statements, the products contain at least two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli @ *** CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)(1)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information in the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other thing, the product contains no more than 360 mg of sodium.

Furthermore, the Dei Fratelli @ *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(1)(A) of the Act because the labels bear nutrient content claims that are not authorized by regulation for the Act or are not consistent with an authorizing regulation. The claims include "*** a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has define the nutrient content claim "high" in 21 CFR 101.54(b). "High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli @ *** CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared by their common or usual name, as stated in section 403(i)(2) of the Act and 21 CFR 101.4(a)(1). Optional information, such as the term "fresh" is not permitted.

Also, the Dei Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA's policy regarding the use "natural," means that nothing artificial or synthetic has been included in, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen (15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

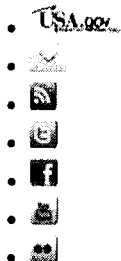
Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

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Oak Tree Farm Dairy, Inc. 16-Aug-01
DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food & Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 11433

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7, 2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - Food Labeling (21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993, copy enclosed). FDA's policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms "100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/

Robert L. Hart

Acting District Director

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10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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Alexia Foods, Inc 11/16/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, Maryland

WARNING LETTER NOV 16, 2011

OVERNIGHT MAIL RETURN RECEIPT REQUESTED

Alex Dzieduszycki, CEO/President
Alexia Foods, Inc.
51-02 21st Street, #3B
Long Island City, New York 11101

Dear Mr. Dzieduszycki:

The U.S. Food and Drug Administration (FDA) has reviewed the labels for your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms products. Based on our review, we have concluded that these products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find copies of the Act and the FDA regulations through links in FDA's home page at <http://www.fda.gov>¹.

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. 343(a)(1)], which states that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular. The phrase "All Natural" appears at the top of the principal display panel on the label. FDA considers use of the term "natural" on a food label to be truthful and non-misleading when "nothing artificial or synthetic...has been included in, or has been added to, a food that would not normally be expected to be in the food." [58 FR 2302, 2407, January 6, 1993].

Your Alexia brand Roasted Red Potatoes & Baby Portabella Mushrooms product contains disodium dihydrogen pyrophosphate, which is a synthetic chemical preservative. Because your products contain this synthetic ingredient, the use of the claim "All Natural" on this product label is false and misleading, and therefore your product is misbranded under section 403(a)(1) of the Act.

We note that your Alexia brand products market a number of food products with the "All Natural" statement on the label. We recommend that you review all of your product labels to be consistent with our policy to avoid additional misbranding of your food products.

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products and labeling comply with the Act and its implementing regulations. You should take prompt action to correct the violations cited in this letter. Failure to do so may result in enforcement action without further notice. Such action may include, but is not limited to, seizure or injunction.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation, such as revised labels or other useful information, that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your written response should be sent to Latasha Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835. If you have any questions, please contact Ms. Robinson at 301-436-1890.

Sincerely yours,
/s/
Michael W. Roosevelt
Acting Director
Office of Compliance

Center for Food Safety
and Applied Nutrition

cc: New York District Office

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